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(54) Buttoned device for the transvenous occlusion of intracardiac defects.

(57) A transcatheter occluding intracardiac defect device comprizes a folding poly-urethane foam(16) with Teflon coated wire skeleton(12), introducible into a long vascular sheath sheath(40) and automatically unfolded upon delivery in the distal to the defect cardiac chamber. A two mm string loop(14) is attached to the center of the occluder(10), while the loop is closed by 1 mm knot(18). A loading wire (28) comprizes a Teflon hollow wire(30) and a double mono-filament thread which carries the occluder on one end and is tied on the other end. An occluder holder(20) comprizes a rhomboid poly-urethane foam with Teflon coated wire skeleton and a "rubber" piece(24) sutured in the center. The occluder-holder(20) is advanced over the the loading wire(28) axis and through the long sheath(40) in the proximal to the defect cardiac chamber and is pushed against the occluder(10) till it is securely buttoned. The distal end of the loading wire(36) is cut and the hollow wire (30) is pulled out over the double thread. The thread is pulled as a single strand and therefore the device is released.

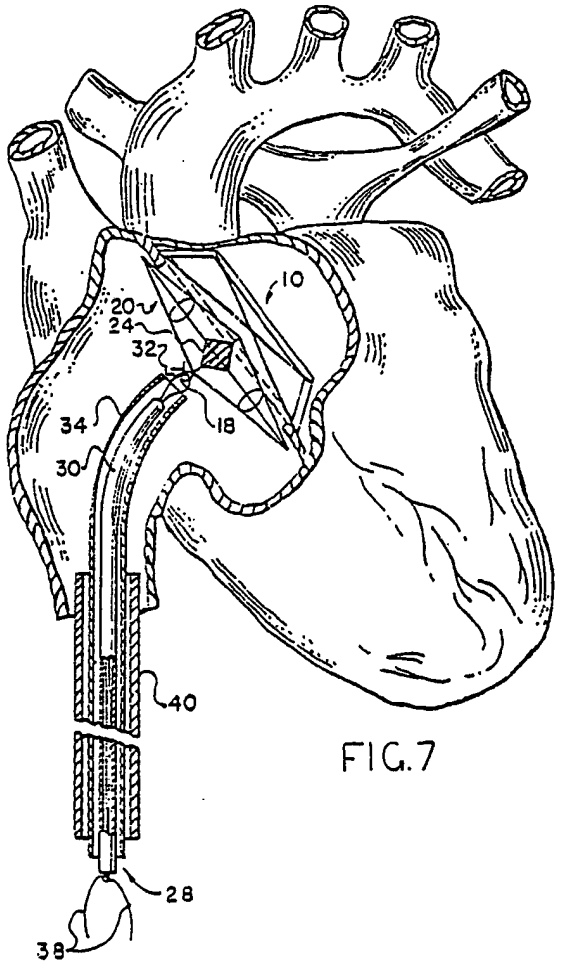

FIG.7

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A 'buttoned' device for the transvenous occlusi n f intracardiac defects

The present invention relates to an intracardiac prosthesis, and more particularly, concerns a transvenously deliverable prosthesis for the occlusion of intracardiac defects.

Intracardiac defects occur relatively uncommonly in children but can cause significant problems including congestive heart failure, pulmonary hypertension or even death. They are treated medically initially but quite frequently require surgical repair.

The surgical repair of intracardiac defects requires the use of general anesthesia, thoracotomy and heart-lung machine. It is associated with significant morbidity and mortality, pain for the child and a significant expense for the parents. For these reasons attempts were made before to close intracardiac defects without surgery. For example see King et al U.S. Pat. 3,874,388.

The late Dr. Rashkind invented an umbrella device with hooks on the inside. The umbrella was introduced by a long catheter in the distal to the defect chamber, it would open there and then would be pulled against the septal wall by the catheter till it was well hooked. Subsdequently, it was released.

The method did not become popular, because it was associated with complications.

none of the above devices were patented. We know though a great deal more about his double disk device, designed to occlude a vessel called patent ductus arteriosus. There are no hooks involved but a bulky delivery system, requiring a very large for a child long sheath (11F or 3.7mm for a 17mm device).

The intracardiac prothesis of the present invention provides the means of the transvenous, without surgery, occlusion of intracardiac defects. The occlusion is achieved by two independently buttoned components, the occluder and the counter-occluder or occluder holder.

In a preferred embodiment of the occluder aspect of this invention, the polyurethane foam with the X shape wire skeleton is folded so that the skeleton wires become nearly parallel. Thus the occluder can be introduced through a 7F (2.3mm) or an 8F(2.7mm) long sheath. The foam has a diameter of 2mm, while the wire is size 0.018-0.025" (0.045-0.06mm). The wire is Teflon covered in order not to be thrombogenic. The occluder is dipped into Heparin solution before the introduction. At the center of the occluder a 2mm long double loop is attached. The loop is closed by a 1mm diameter knot. In actuality this knot will be the "button" during the attachment with the counter-occluder.

Another aspect of the present invention is the counter-occluder, or occluder holder. It is rhomboid in shape, made also by 2mm thick polyurethane foam and a single 0.018"(0.045mm) wire of equal diameter to the occluder. Foam and wire are stitched together by a continuously run suture. A 2mm rubber piece of rhomboid shape is sutured at the center of the occluder-holder. By applying two sutures along the rubber piece, the foam is covering the rubber, so there is no friction during the introduction and the advancement of the occluder-holder in the long sheath. A further aspect of the present invention is the release or loading wire. It comprizes a Teflon coated hollow wire of a 0.028"-(0.07mm) wire and a double 0.05"(0.017mm) Trilene thread, attached on the one end at already described occluder loop and tied on the other end of the hollow wire.

Trilene is a trademark and identifies a synthetic mono-filament fishing line of thread. The loading wire is used:

1. To pull the occluder against the septum.
2. To load the occluder-holder by threading the wire through the rubber center of the occluder-holder.
3. As the axis of the pushing catheter and the long sheath, so the occluder-holder is pushed and is buttoned securely against the occluder.
4. To release the device, by cutting its distal end, pulling the hollow wire over the double Trilene thread and then pulling the thread as a single strand.

In accordance with the principles of the present invention, the intracardiac prosthesis hereof has significant advantages over known devices and specificaly the Rashkind device and the King et al '388 device. It is miniaturized in size, requires a 7F (2.3mm) or 8F (2.7mm) sheath in comparison to a 15F (5.0mm) sheath for the Rashkind device or a 23F (7.5mm) sheath for a King et al device. It does not utilize hooks so it is not traumatic to the endocardium, or the conduction system. It conforms with the overall applicability of this intracardiac device to small children.

FIG. 1. is a perspective view of the preferred embodiment of the intracardiac prosthesis part of the occluder, illustrated in the unfolded condition.

FIG. 2. is a perspective view of the preferred embodiment of the intracardiac prosthesis part of the occluder, illustrated in the folded condition, ready to be introduced in the long sheath.

FIG. 3. is a perspective view of the occluder connected through the central loop with the loading wire.

FIG. 4. is a perspective view of the intracar-

diac prosthesis part of the counter-occluder or occluder holder.

FIG. 5. is a cross-sectional view of the intracardiac device part of the occluder, connected to the loading wire and occluding an atrial septal defect.

FIG. 6. is a cross-sectional view of the intracardiac device part of the occluder-holder as it is introduced into the long sheath, over the loading wire.

FIG. 7. is a cross-sectional view of the occluder and occluder-holder parts of the device buttoned together and occluding the atrial septal defect.

FIG. 8. is a cross-sectional view of the detachment of the intracardiac device in the heart and removal of the loading wire and the long sheath.

While this invention is satisfied by embodiments in many forms, will herein be described in detail a preferred embodiment of the invention, with the understanding that the present disclosure is not intended to limit the invention to the embodiment illustrated. Referring to the drawings, and FIG. 1 in particular, there is illustrated the preferred intracardiac prosthesis part, the occluder 10, of the present invention in the unfolded condition.

The occluder 10 is made by polyurethane foam 16 lining 2mm thick, with a diameter of 10mm more than the diameter of the defect to be occluded. A Teflon coated wire skeleton 12 is introduced into the foam in an X shape and securely stitched to the foam by continuous and interrupted sutures.

A double loop thread or threaded loop 14 is securely attached at the center of the wire skeleton. The length of the loop is 2mm and is closed by a knot of 1mm in diameter.

In FIG. 2 which illustrates the occluder 10 folded, it becomes obvious how by applying gentle pressure on the edges of the wire skeleton between the thumb and the index finger, the occluder can be introduced into the long intravascular sheath 40. The long sheath can be as small as 7 or 8F in diameter so the device can be introduced through the vessels of small children. Turning now to FIG.3, the occluder 10 is connected to loading wire 28. The loading wire 28 consists of hollow wire 30 of a 0.028" Teflon coated wire and the double 005" Trilene mono-filament thread 32. The mono-filament thread 32 is passed through the "button"loop 14 attached to the occluder 10 and then through the hollow wire 30 in a double fashion. (FIG. 3 and 6) .Mono-filament thread 32 is tightened several times at distal end 36, of the loading wire 28, so it is stretched inside the hollow wire 30.

A 3cm thread end 38 is left after the knot at the distal end 36 in the mono-filament thread 32, to facilitate the future introduction of the occluder-holder 20 over the wire 28. The loading wire 28 serves several purposes as it has been described before, pulling the occluder 10 against the septum, serving as the loading axis of the occluder-holder 20 and finally incorporating the release mechanism of the intracardiac device.

FIG. 4 describes the occluder-holder 20 which is also made by 2mm thick foam 22. The length of the occluder-holder 20 is selected as equal to length of the occluder 10. Skeleton 26 is made by 0.018" (0.045mm) Teflon coated wire to avoid clot formation. Wire 26 and foam 22 are stitched together by continuous and interrupting sutures.

On the center of the occluder-holder 20 a 2mm rubber rhomboid piece 24 is sutured. It serves several purposes. Firstly allows the occluder-holder 20 to be moved on the loading wire 28 axis without danger of dislodgement. Secondly it has elastic properties, so it is distened to allow the button knot 18 through. Thirdly it serves as the button-hole, so that it does not allow the knot 18 to un-botton after detachment, thus holding the occluder 10 and occluder-holder 20 together.

Two stitches sutured along the rubber button allow the rubber 24 to be covered by foam 22. Thus, the friction is minimized during the introduction and the advancement into the long sheath 40.

FIG. 5 describes the introduction and the positioning of the occluder 10 inside the heart. The folded occluder is introduced as described before into the long sheath 40. A 7F end-hole catheter 34 is introduced over the loading wire 28 into the long sheath 40 and it is pushing the occluder 10 till it exits in the cardiac chamber distant to the cardiac defect. After the occluder 10 comes out from the long sheath 40, it is automatically unfolded and pulled gently with the loading wire 28 against the septal wall where the occluder is loosely attached.

FIG. 6 describes the introduction of the occluder-holder 20 inside the long sheath 40. The loading wire 28 is threaded through the center of the rubber piece 24 of the occluder-holder. The occluder-holder 20 is then advanced over the loading wire 28 and it is introduced into the long sheath 40. The 7F end-hole catheter 34 is introduced over the loading wire 28, pushing the occluder-holder, till it exits the long sheath 40 in the proximal to the defect cardiac chamber.

FIG. 7 illustrates the attachment of the occluder 10 to the occluder-holder 20. The occluder-holder has exited the sheath 40 and is pushed by the end-hole catheter 34 in a parallel fashion to the defect and the occluder, but still on the loading wire 28 axis. The loading wir is pulled gently, whil the occluder-holder 20 is pushed by the end-hole catheter 34 and the nd of the sheath 40. The actual "button" process involves the entry of the knot 18

of the occluder loop 14 into the rubber center 24 of the occluder-holder and the attachment by the "valve" like action.

FIG. 8 illustrates the detachment. The end of the loading wire 28 is cut. A sterilized pair of small pliers is used to cut the end of the hollow wire 30 and the tightened double 0.005"(0.017mm) mono-filament thread 32 which are located outside the body. Thus they become detached from each other and they are removed with the following mechanism:

The hollow wire 30 is pulled out over the double 0.005"(0.0127mm) mono-filament thread 32. The thread 32 is subsequently pulled out as a single strand, so that the device is detached inside the heart after the defect is occluded. The present invention provides a percutaneous deliverable intracardiac prosthesis, suitable for treatment of various intracardiac defects, including atrial septal defect, ventricular septal defect and cardiac defects as parts of more complex lesions.

As an aid to correlating the terms of the claims to the exemplary drawing, the following catalog of elements and steps is provided:

10 occluder
12 skeleton
14 thread loop
16 polyurethane disc
18 knot
20 counter-occluder or occluder holder-rhomboid
22 polyurethane disc - (holder)
24 rubber piece - rhomboid
26 skeleton
28 loading wire
30 hollow wire or tube
32 Trilene thread
34 catheter
36 Distal end
38 Thread end
40 long sheath

Claims

1. An intracardiac percutaneously deliverable device for the repair of heart defects comprising:
an occluder(10), said occluder including:
i. a foldable foam polyurethane dis[illegible]6) with
ii. Teflon coated wire skeleton (12) in the form of an "X" sutured to the foam disc, and
iii. a thread(14) sutured to the center of the wire skeleton,
iv. said thread formed into a loop with
v. a knot(18) closing the loop remote from the skeleton,
an occluder-holder(20), said occluder-holder including:
i. a foldable foam polyurethane rhomboid disc with
ii. a single wire skeleton sutured to the rhomboid disc, and
iii. a rubber piece (24) sutured at the center of the rhomboid disc,
a loading wire(28) including:
i. a Teflon coated hollow wire(30), and
ii. a long thread,
said loading wire pierced throught and opening in the occluder-holder and its rubber piece,
said long thread extending
i. through the hollow wire,
ii. throught the thread loop at the occluder, and
iii. back through the hollow wire;
so arranged and constructed that
i. the occluder-holder(20) may be pushed toward the occluder(10) and
ii. pulling on the loading wire will pull the knot(18) through the rubber piece(24) of the occluder-holder(20) thereby
iii. buttoning the occluder-holder(10) to the occluder-holder(20).

2. The process of occluding a defect in a heart in which an occluder(10) is placed on one side of the defect and an occluder-holder(20) is placed on the other side of the defect; wherein an improved method of connecting the occluder and occluder-holder comprises:
before placing the occluder in the heart
i. attaching a loop of thread(14) to the occluder,
ii. knotting the loop, and
iii. piercing the occluder-holder,
then after placing the occluder and occluder-holder in place
i. pulling the knot(18) through the pierced occluder-holder thereby
ii. buttoning the occluder(10) to the occluder-holder(20).

3. The invention as described in claim 2: wherein said occluder-holder(20) is pierced by a loading wire(28) which
is used to place the occluder-holder,
then after the occluder holder is buttoned to the occluder:
i. cutting the loading wire,
ii. removing the loading wire, and
iii. removing a long doubled thread (32)-extending through the loop on the occluder by
iv. pulling one end of said doubled thread.

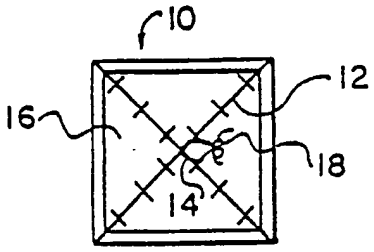

FIG.1

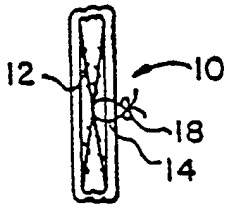

FIG.2

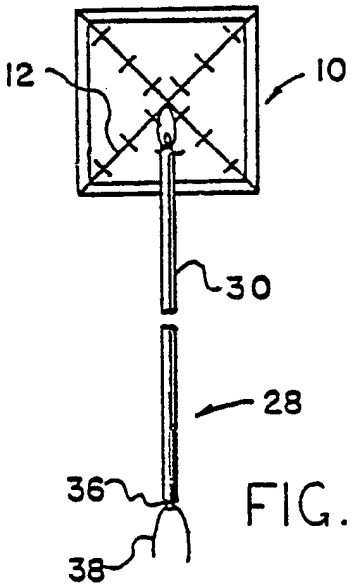

FIG.3

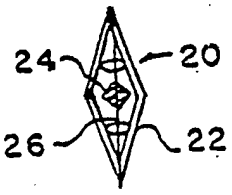

FIG.4

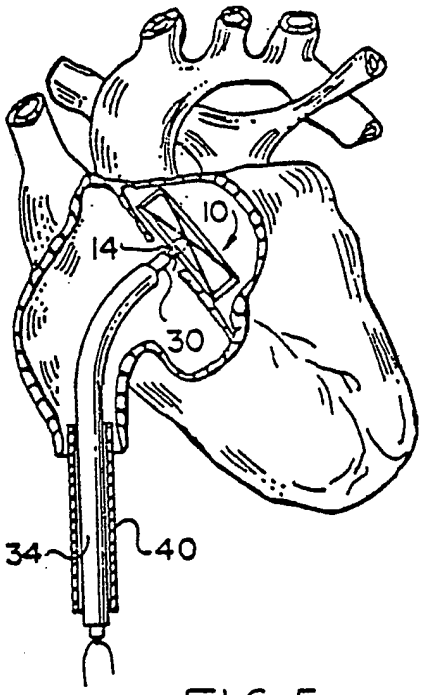

FIG.5

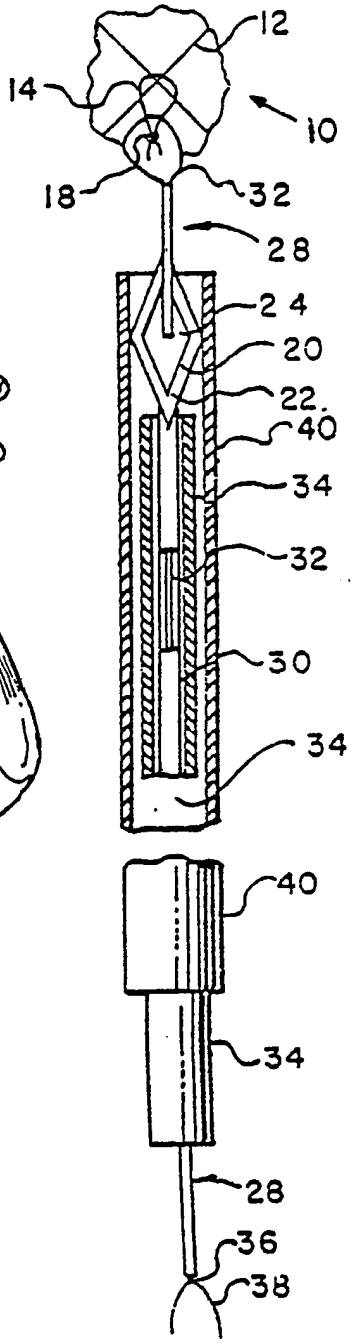

FIG.6

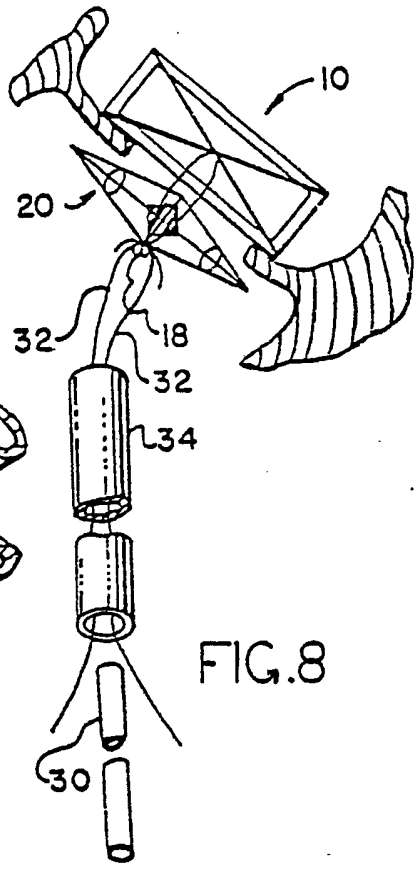

FIG.8

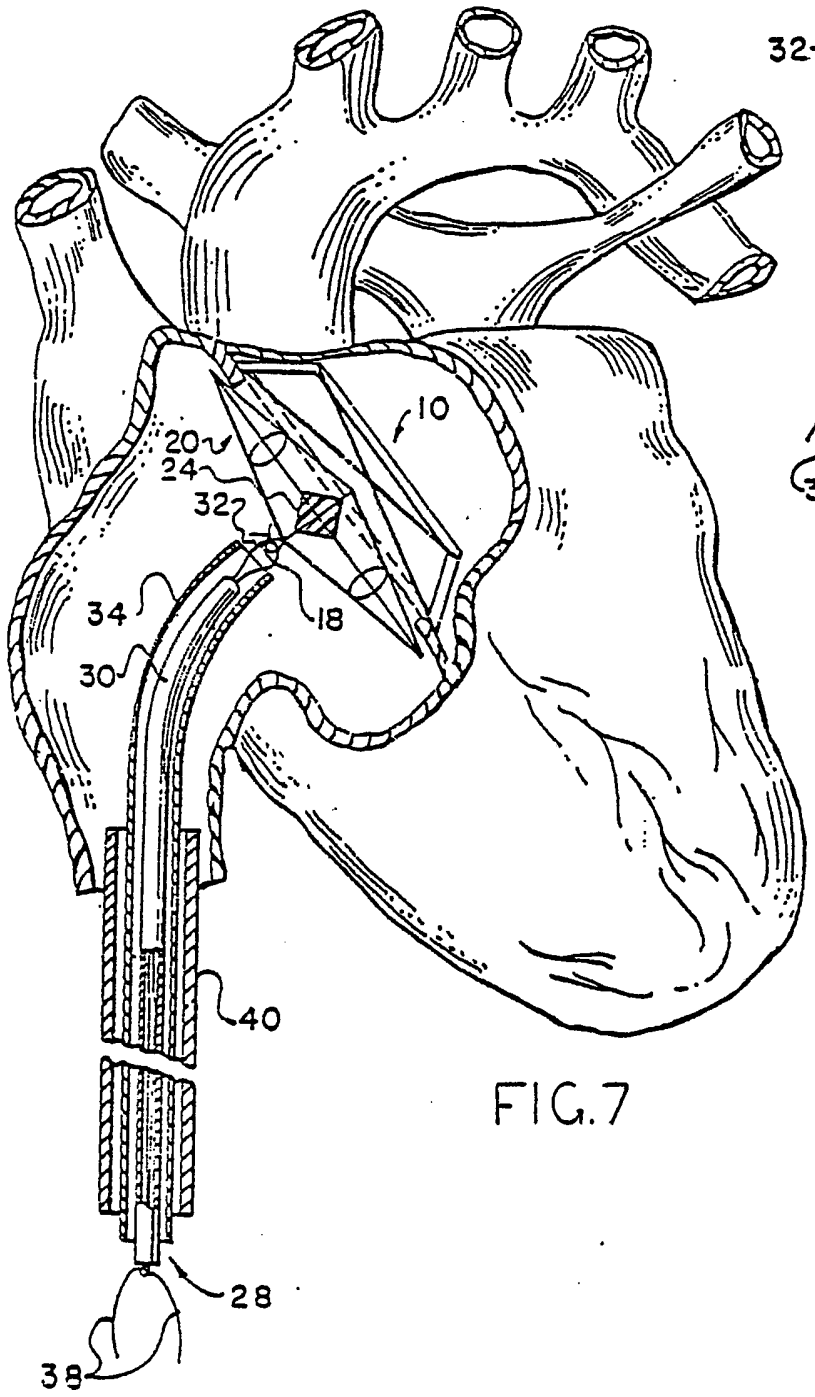

FIG.7

European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 89 60 0014

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
A	DE-A-2 822 603 (THIERFELDER) * Figures; page 10, line 1 - page 12, line 10 *	1-3	A 61 F 2/24
D,A	US-A-3 874 388 (KING) * Whole document *	1	

TECHNICAL FIELDS SEARCHED (Int. Cl.5)

A 61 F
A 61 B

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	20-11-1989	STEENBAKKER J.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

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(12) # EUROPEAN PATENT SPECIFICATION

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(56) References cited :
DE-A- 2 822 603
US-A- 3 874 388

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Description

The present invention relates to an intracardiac prosthesis, and more particularly, concerns a transvenously deliverable prosthesis for the occlusion of intracardiac defects as specified in the preamble of Claim 1. Such a device is known e.g. from US-A-3 874 388.

Intracardiac defects occur relatively uncommonly in children but can cause significant problems including congestive heart failure, pulmonary hypertension or even death. They are treated medically initially but quite frequently require surgical repair.

The surgical repair of intracardiac defects requires the use of general anesthesia, thoracotomy and heart-lung machine. It is associated with significant morbidity and mortality, pain for the child and a significant expense for the parents. For these reasons attempts were made before to close intracardiac defects without surgery.For example see King et al U.S. Pat. 3,874,388. Dr. King's device was a two disk device. Both disks were connected to a catheter. Since both. disks needed to be introduced simultaneously, a large introducing sheath (7.5mm in diameter) was required, which made the application to children difficult. The release mechanism was also complex. Dr.King applied his device in a few adults. However the method was never popularized.

The late Dr. Rashkind invented an umbrella device with hooks on the inside. The umbrella was introduced by a long catheter in the distal to the defect chamber, it would open there and then would be pulled against the septal wall by the catheter till it was well hooked. Subsdequently, it was released.

The method did not become popular, because it was associated with complications. Dr. Rashkind invented also a hookless two disk device. However details of the specifications are not known and none of the above devices was patented. We know though a great deal more about his double disk device, designed to occlude a vessel called patent ductus arteriosus. There are no hooks involved but a bulky delivery system, requiring a long sheath (11F or 3.7mm for a 17mm device) which is very large for a child.

The intracardiac prothesis of the present invention provides the means of the transvenous, without surgery, occlusion of intracardiac defects. The occlusion is achieved by two independently buttoned components, the occluder and the counter-occluder or occluder holder as specified in Claim 1.

In the occluder of this invention, the polyurethane foam with the X shape wire skeleton is folded so that the skeleton wires become nearly parallel. Thus the occluder can be introduced through a 7F (2.3mm) or an 8F (2.7mm) long sheath. The foam has a diameter of 2mm, while the wire is size 0.018-0.025" (0.045-0.06cm). The wire is polyt trafluorethylene covered in order not to be thrombogenic. The occluder is dipped into Heparin solution before the introduction. At the center of the occluder a 2mm long double loop is attached. The loop is closed by a 1mm diameter knot. In actuality this knot will be the "button" during the attachment with the counter-occluder.

Another aspect of the present invention is the counter-occluder, or occluder holder. It is rhomboid in shape, made also by 2mm thick polyurethane foam and a single 0.018" (0.045cm) wire of equal diameter to the occluder. Foam and wire are stitched together by a continuously run suture. A 2mm rubber piece of rhomboid shape is sutured at the center of the occluder-holder. By applying two sutures along the rubber piece, the foam is covering the rubber, so there is no friction during the introduction and the advancement of the occluder-holder in the long sheath.A further aspect of the present invention is the release or loading wire. It comprizes a polytetrafluorethylene coated hollow wire of a 0.028" (0.07cm) wire and a double 0.005" (0.017cm) Trilene thread, attached on the one end at already described occluder loop and tied on the other end of the hollow wire.

Trilene is a trademark and identifies a synthetic mono-filament fishing line of thread. The loading wire is used:

1. To pull the occluder against the septum.
2. To load the occluder-holder by threading the wire through the rubber center of the occluder-holder.
3. As the axis of the pushing catheter and the long sheath, so the occluder-holder is pushed and is buttoned securely against the occluder.
4. To release the device, by cutting its distal end, pulling the hollow wire over the double Trilene thread and then pulling the thread as a single strand.

In accordance with the principles of the present invention, the intracardiac prosthesis hereof has significant advantages over known devices and specificaly the Rashkind device and the King et al '388 device. It is miniaturized in size, requires a 7F(2.3mm) or 8F(2.7mm) sheath in comparison to a 15F (5.0mm) sheath for the Rashkind device or a 23F (7.5mm) sheath for a King et al device. It does not utilize hooks so it is not traumatic to the endocardium, or the conduction system. It conforms with the overall applicability of this intracardiac device to small children.

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FIG. 7. is a cross-sectional view of the occluder and occluder-holder quarts of the device buttoned together and occluding the artial septal defect.

FIG. 8. is a cross-sectional view of the detachment of the intracardiac device in the heart and removal of the loading wire and the long sheath.

While this invention is satisfied by embodiments in many forms, a preferred embodiment of the invention will herein be described in detail, with the understanding that the present disclosure is not intended to limit the invention to the embodiment illustrated. Referring to the drawings, and FIG. 1 in particular, there is illustrated the preferred intracardiac prosthesis part, the occluder 10, of the present invention in the unfolded condition.

The occluder 10 is made by polyurethane foam 16 lining 2mm thick, with a diameter of 10mm more than the diameter of the defect to be occluded. A polytetrafluorethylene coated wire skeleton 12 is introduced into the foam in an X shape and securely stitched to the foam by continuous and interrupted sutures.

A double loop thread or threaded loop 14 is securely attached at the center of the wire skeleton. The length of the loop is 2mm and is closed by a knot 18 of 1mm in diameter.

In FIG. 2 which illustrates the occluder 10 folded, it becomes obvious how by applying gentle pressure on the edges of the wire skeleton between the thumb and the index finger, the occluder can be introduced into the long intravascular sheath 40. The long sheath can be as small as 7 or 8F in diameter so the device can be introduced through the vessels of small children. Turning now to FIG. 3, the occluder 10 is connected to loading wire 28. The loading wire 28 consists of hollow wire 30 of a 0.028" (0.07cm) polytetrafluorethylene coated wire and the double 0.005" (0.013cm) Trilene mono-filament thread 32. The mono-filament thread 32 is passed through the "button" loop 14 attached to the occluder 10 and then through the hollow wire 30 in a double fashion. (FIG. 3 and 6). Mono-filament thread 32 is tightened several times at distal end 36, of the loading wire 28, so it is stretched inside the hollow wire 30.

A 3cm thread end 38 is left after the knot at the distal end 36 in the mono-filament thread 32, to facilitate the future introduction of the occluder-holder 20 over the wire 28. Th loading wire 28 serv s s veral purpos s as it has been d scrib d before, pulling the occlud r 10 against the septum, s rving as the loading axis of th occluder-holder 20 and finally incorporating the rel ase mechanism of the intracardiac device.

FIG. 4 describes the occluder-holder 20 which is also made by 2mm thick foam 22. The length of the occluder-holder 20 is selected as equal to length of the occluder 10. Skeleton 26 is made by 0.018" (0.045cm) polytetrafluorethylene coated wire to avoid clot formation. Wire 26 and foam 22 are stitched together by continuous and interrupting sutures.

On the center of the occluder-holder 20 a 2mm rubber rhomboid piece 24 is sutured. It serves several purposes. Firstly allows the occluder-holder 20 to be moved on the loading wire 28 axis without danger of dislodgement. Secondly it has elastic properties, so it is distened to allow the button knot 18 through. Thirdly it serves as the button-hole, so that it does not allow the knot 18 to un-botton after detachment, thus holding the occluder 10 and occluder-holder 20 together.

Two stitches sutured along the rubber button allow the rubber 24 to be covered by foam 22. Thus, the friction is minimized during the introduction and the advancement into the long sheath 40.

FIG. 5 describes the introduction and the positioning of the occluder 10 inside the heart. The folded occluder is introduced as described before into the long sheath 40. A 7F end-hole catheter 34 is introduced over the loading wire 28 into the long sheath 40 and it is pushing the occluder 10 till it exits in the cardiac chamber distant to the cardiac defect. After the occluder 10 comes out from the long sheath 40, it is automatically unfolded and pulled gently with the loading wire 28 against the septal wall where the occluder is loosely attached.

FIG. 6 describes the introduction of the occluder-holder 20 inside the long sheath 40. The loading wire 28 is threaded through the center of the rubber piece 24 of the occluder-holder. The occluder-holder 20 is then advanced over the loading wire 28 and it is introduced into the long sheath 40. The 7F end-hole catheter 34 is introduced over the loading wire 28, pushing the occluder-holder, till it exits the long sheath 40 in the proximal to the defect cardiac chamber.

FIG. 7 illustrates the attachment of the occluder 10 to the occluder-holder 20. The occluder-holder has exited the sheath 40 and is pushed by the end-hole catheter 34 in a parallel fashion to the defect and the occluder, but still on the loading wire 28 axis. The loading wire is pulled gently, while the occluder-holder 20 is pushed by the end-hole catheter 34 and the end of the sheath 40. The actual "button" process involves the entry of the knot 18 of the occluder loop 14 into the rubber center 24 of the occluder-holder and the attachm nt by th "valve" lik action.

FIG. 8 illustrat s the detachm nt. Th nd of the loading wire 28 is cut. A steriliz d pair of small pliers is used to cut th end of th hollow wir 30 and the tightened double 0.005" (0.017cm)mono-filament

thread 32 which are located outside the body. Thus they become detached from each other and they are removed with the following mechanism:
The hollow wire 30 is pulled out over the double 0.005" (0.0127cm) mono-filament thread 32. The thread 32 is subsequently pulled out as a single strand, so that the device is detached inside the heart after the defect is occluded. The present invention provides a percutaneous deliverable intracardiac prosthesis, suitable for treatment of various intracardiac defects, including atrial septal defect, ventricular septal defect and cardiac defects as parts of more complex lesions.

As an aid to correlating the terms of the claims to the exemplary drawing, the following catalog of elements and steps is provided:

10	occluder
12	skeleton
14	thread loop
16	polyurethane disc
18	knot
20	counter-occluder or occluder holder-rhomboid
22	polyurethane disc - (holder)
24	rubber piece - rhomboid
26	skeleton
28	loading wire
30	hollow wire or tube
32	Trilene thread
34	catheter
36	Distal end
38	Thread end
40	long sheath

Claims

1. An intracardiac percutaneously deliverable device for the repair of heart defects comprizing a pair of cooperating foldable members each comprising a wire skeleton and polyurethane foam, and a loading wire (28) including a hollow wire (30), characterized in that the first of said cooperating foldable members is an occluder (10), said occluder including:
   i. a foldable foam polyurethane disk (16) with
   ii. polytetrafluorethylene coated wire skeleton (12) in the form of an "X" sutured to the foam disk, and
   iii. a thread (14) sutured to the center of the wire skeleton,
   iv. said thread formed into a loop with
   v. a knot (18) closing the loop remote from the skeleton, whereas the second of said cooperating foldable members is an occluder-holder (20), said occlud r-holder including:
      i. a foldabl foam polyurethan rhomboid disc with
      ii. a singl wire skeleton sutured to the rhomboid disc, and
      iii. a rubber piece (24) sutured at the center of the rhomboid disc, said loading wire (28) including:
         i. a polytetrafluorethylene coated hollow wire (30), and
         ii. a long thread, said loading wire (30) being capable of being pierced through an opening in the occluder-holder in its rubber piece,
         said long thread extending
            i. through the hollow wire,
            ii. through the thread loop of the occluder, and
            iii. back through the hollow wire;
            so arranged and constructed that
               i. the occluder-holder (20) may be pushed by an end-hole catheter (34) along the loading wire (28) towards the occluder (10) at the distal end of the said loading wire (28) and
               ii. pulling on the loading wire while holding catheter (34) in a counteracting manner will pull the knot (18) through the rubber piece (24) of the occluder-holder(20) thereby
               iii. buttoning the occluder (10) to the occluder holder (20).

Patentansprüche

1. Ein endokardiales Gerät zur Heilung der Herzerkraukungen, das perkutan eingeführt wird und aus zwei zusammenarbeitenden faltbaren Gliedern besteht. Ein jedes Glied besteht aus einem Drahtgestell und aus Polyurethane. Das Gerät enthält auch einen Lastdraht (28), der einen gehöhlten Draht (30) umfaßt, und prägt sich dadurch aus, daß das erste der besagten zusammenarbeitenden faltbaren Glieder ein Verschließer (10) ist,
   der besagte Verschließer umfaßt:
      i. eine faltbare Scheibe aus Polyurethane (16) mit
      ii. Drahtgestell (12), das mit TEFLON belegt ist, die Form eines "X" hat und mit der Scheibe zusammengenäht ist und
      iii. einen Faden (14), der mit dem Mittelpunkt des Drahtgestells zusammengenäht ist,
      iv. den besagten Faden, der zu einer Schleife geform ist mit
      v. inen knoten (18), d r die Schleif entfernt von dem Drahtgestell schließt, während das zweit d r besagten zusamm narbeitenden faltbaren Gliedern ein Halter (20) des Ver-

schließers ist,
der besagte Halter des Verschli ßers umfaßt:
i. eine faltbare rautenförmig Scheibe aus Polyurethane mit
ii. ein einzelnes Drahtgestell, das mit der rautenförmigen Scheibe zusammengenäht ist,
iii. ein Stück aus Gummi (24), das mit dem Mittelpunkt der rautenförmigen Scheibe zusammengenäht ist,
der besagte Lastdraht (28) umfaßt:
i. einen gehöhlten Draht (30), der mit TEFLON belegt ist und
ii. einen langen Faden,
der besagte Lastdraht (28) kann durch eine Öffnung des Halters (20) gedrungen werden und zwar durch eine Öffnung seines Stücks aus Gummi,
der besagte lange Faden dringt
i. durch den gehöhlten Draht
ii.durch die Schleife des Verschließers und
iii. wieder durch den gehöhlten Draht,
das Gerät hat solche Anordnung, daß
i. der Halter des Verschließers durch einen Katheter (34) eutlang dem Lastdraht (28) zu dem Verschlie er (10) geschoben werden kann,
ii. Wenn der Lastdraht gerogen wird, wird der Knoten (18) auch durch das Stück aus Gummi (24) des Halters (20) gerogen vorausgesetzt, daß der Katheter (34) festgehalten ist, Auf diese Weise,
iii. werden der Verschließer (10) und der Halter des Verschließers (20) miteinander geknöpft.

Revendications

1. Un appareil intracardiaque, qui est introduit à travers la peau pour la réparation des defaillances cardiaques. Cet appareil comprend une paire de membres coopérés et pliants. Chacun de ces membres comprend un squelette de fil metallique et polyurethane. L' appareil comprend aussi un fil métallique de chargement (28), qui contient un fil métallique perforé (30) et qu'il se caractérise par le fait que le premier de membr s dites est un obstrueur (10), l'obstrueur dit conti nt:
i. un disque pliant de polyur thane (16) av c
ii. un squelette de fil métallique couvert d TEFLON (12) dont la forme est un "X" et qui est cousu au disque et
iii. un fil (14) cousu au centre du squelette de fil métallique,
iv. le fil dit, formé comme un noeud coulant avec
v. un noeud (18), qui ferme le noeud coulant loin du squelette, taudis que le deuxième de ces membres dites est un support du obstrueur (20), le support du obstrueur dit contient:
i. un disque rhomboîdal et pliant, de polyurethane avec
ii. un squelette de fil métallique particulier, qui est cousu au disque rhomboîdal, et
iii. une pièce de caoutchouc (24), qui est cousue au centre du disque rhomboîdal,
le fil métallique de chargement (28) dit centient:
i. un fil métallique perforé (30) couvert de TEFLON, et
ii. un fil long,
le fil métallique de chargement (28) dit est capable de pénétrer à travers une ouverture du support du obstrueur, l'ouverture se trouve à la pièce de caoutchouc,
le fil long dit, pénétre:
i. à travers le fil métallique perforé,
ii. à travers le noeud conlant du obstrueur, et
iii. eucore une fois à travers le fil métallique perforé,
l'appareil est arrangé et construit de maniére que:
i. le support du obstrueur (20) pent être poussé par un catheter (34) le long de fil métallique de chargement (28) vers le obstrueur (10) et
ii. en tirant le fil métallique de chargement peudant que le cathéter (34) est tenu fixe, le noeud (18) sera tiré à travers la pièce de caoutchouc (24) du support du obstrueur (20) et de cette manière
iii. le obstrueur (10) et le support du obstrueur (20) sont bouttonès mutuellement.

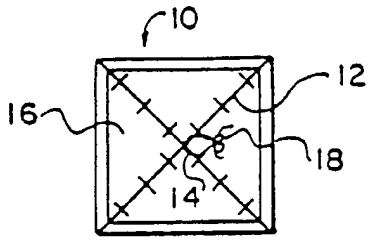

FIG.1

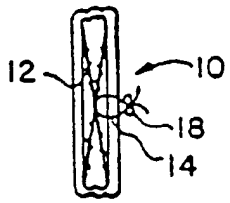

FIG.2

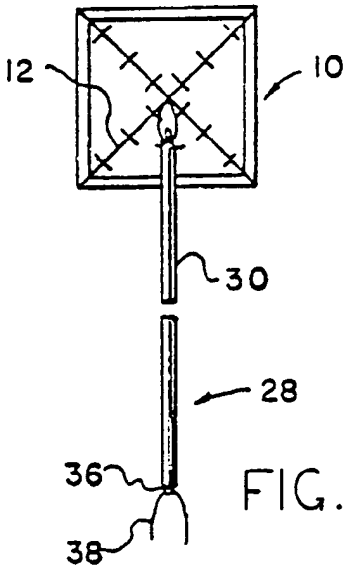

FIG.3

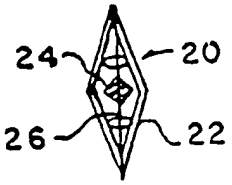

FIG.4

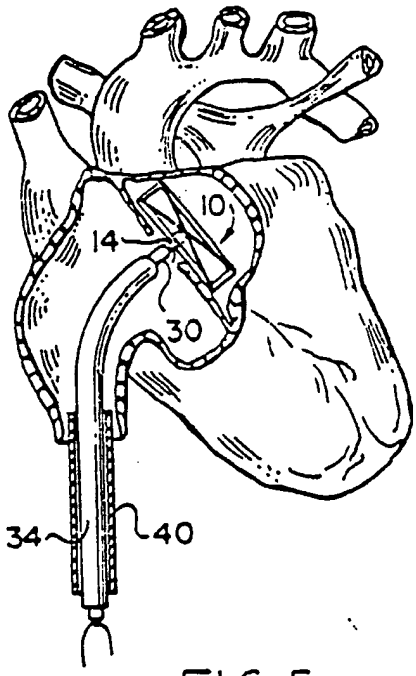

FIG.5

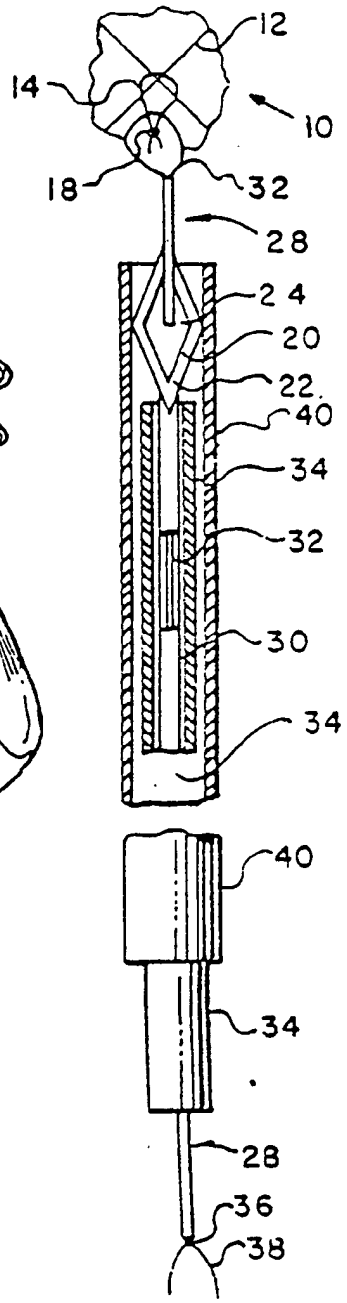

FIG.6

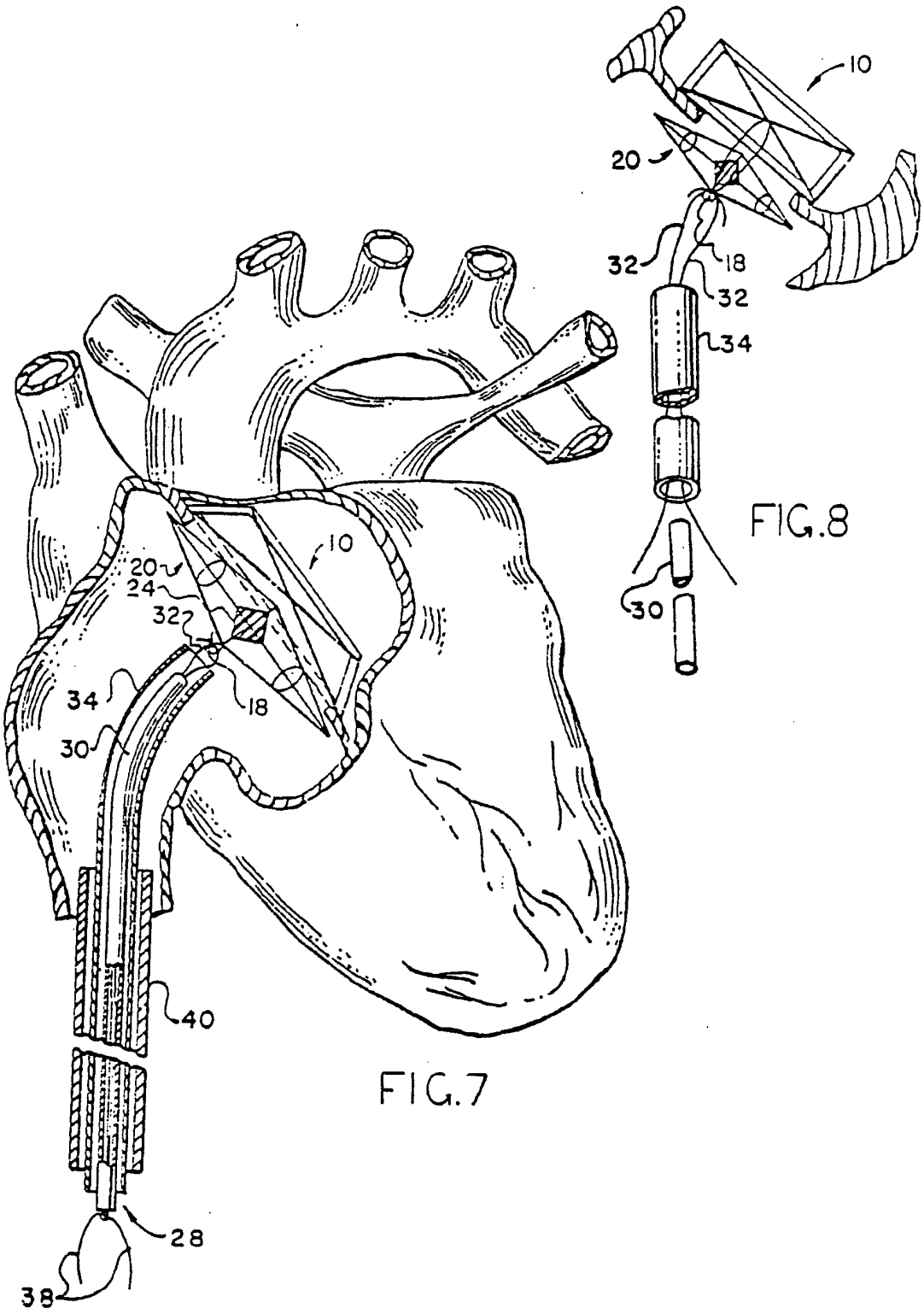

FIG.8

FIG.7